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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,306	04/01/2004	Emanuela Keller	KELLER, E. ET AL. - 1	8572

25889 7590 01/04/2007  
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EXAMINER
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LAURITZEN, AMANDA L

ART UNIT	PAPER NUMBER
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3737

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p>10/816,306</p>	<p><b>Applicant(s)</b></p> <p>KELLER ET AL.</p>	
	<p><b>Examiner</b></p> <p>Amanda L. Lauritzen</p>	<p><b>Art Unit</b></p> <p>3737</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>16 Sept 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

1. Applicant's claim for the benefit of a prior-filed German Application No. 103 15 574.0 filed Apr. 5, 2003 is acknowledged under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4, 7-9, 11-16, 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pfeiffer et al. (U.S. 6,223,069).

Pfeiffer et al. disclose a device for measuring cerebral blood flow using an injection of indocyanine green as an indicator for near infrared spectroscopy (abstract; col. 2, lines 6-7). The method and Pfeiffer is specific to emitting and detecting radiation at first and second locations, respectively (see measurement through both brain hemispheres cited at col. 2, lines 44-45). The arterial dye curve and cerebral dye curve are taken to be inflow and outflow functions as defined by applicant and inherently correspond to non-pulsatile and pulsatile components of the signal (see arterial and cerebral curves at col. 5, lines 1-10). The optical density is monitored to determine an inflow function according to the change in dye concentration with respect to time (effectively the derivative) in the tissue (col. 4, lines 34-37). The convolution integral defines an outflow function (col. 5, line 10). The mean transit time is specified in determination of the

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inflow function and “varying rates” imply variation of transit times (col. 5, lines 40-49). The process of determining the inflow function is deemed iterative (col. 5, line 19). Pfeiffer et al. disclose using blood flow and mean transit time to determine the volume (col. 8, lines 13-15), with a flow parameter by definition being a quotient of volume and time (col. 5, line 33 for ml/min for a flow transport function). The auxiliary variable of the integral provides a scaling factor (col. 5, lines 10-11). The method of Pfeiffer includes an iterative determination of the inflow function that is represented as a sum of a finite number of functions that are similar in form to the transport function (col. 5, lines 38 for the transport function and line 52 for the summation).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 3, 5, 6, 10, 17, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer '069 in view of Boas (U.S. 6,516,214).

Pfeiffer discloses all features of the invention as substantially claimed but is silent with regard to the steps of using a threshold value, extrapolation of a scaled inflow function, and applying a locally increased contact pressure, but in the same field of endeavor, Boas discloses establishing a threshold for dye concentration comparison (col. 3, lines 2-7), extrapolating the position from the scaled inflow function for determining the location of an ischemic event (col. 3, lines 27-39), and applying contact pressure (see flexible cap 400 with rubber grommets 440

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that generates pressure in order to fix the device to the patient's scalp; also col. 10, lines 20-42).

It would have been obvious to one of ordinary skill in the art at the time of invention to include the steps of using a threshold value for comparison purposes and extrapolation of data for determining location as taught by Boas with the method of Pfeiffer in order to evaluate an ischemic event (abstract; also col. 3, lines 13-14).

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



A.L.L.  
12/20/2006



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SUPERVISORY PATENT EXAMINER